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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,772	12/03/2003	David D. Nolle	12258-0021	4208

25267 7590 09/26/2008
BOSE MCKINNEY & EVANS LLP
111 MONUMENT CIRCLE, SUITE 2700
INDIANAPOLIS, IN 46204

EXAMINER

RAMILLANO, LORE JANET

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

09/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/726,772

Applicant(s)

NOLTE ET AL.

Examiner

LORE RAMILLANO

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/13/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-18 and 45-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-18 and 45-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/3/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Applicant's reply filed on 6/13/08 is acknowledged. Claims 12-18 and 45-57 are pending and under examination.

Claim Objections

2. The objection to claim 15 is withdrawn.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 12-14, 18, and 53-57** are rejected under 35 U.S.C. 102(b) as being anticipated by Klein et al. ("Klein," US 5900935).

Klein discloses a device including: a substrate (i.e. fig. 1, 26) including a first plurality of spaced-apart regions configured to bind the first analyte; an optical source (i.e. fig. 1, 30) configured to generate a probe beam which illuminates the first plurality of spaced-apart regions in a sequential manner and interacts with the substrate to form a signal beam; an interferometer (fig. 1, 10) configured to combine with an adaptive optical element a reference beam and the signal beam, the combination of the reference beam and the signal beam generating an output beam; and a detector (i.e. fig. 1, 46) configured to detect the presence or absence of the first analyte based upon the output beam.

Klein further discloses the following: the probe beam is reflected by the substrate to form the signal beam; the probe beam is transmitted through the substrate to form the signal beam; the interferometer operates in a quadrature condition; the interferometer includes an adaptive holographic element; the substrate includes a first surface lying substantially in a first plane and a second surface lying substantially in a second plane, the first plane being offset vertically from the second plane, each of the first plurality of regions lying on the first surface; and wherein the optical source is positioned relative to the substrate such that when the probe beam is directed at one of the first plurality of regions an interference characteristic is produced; a first portion of the probe beam interacts with a target portion of the first surface holding one of the first plurality of regions, and a second portion of the probe beam interacts with a portion of the second surface adjacent to the target portion of the first surface, the first and second portions of the probe beam being combined to produce the output beam, the output beam having a first form when the first analyte is not bound to the target portion of the first surface and a second form when the first analyte is bound to the target portion of the first surface; the output beam includes the first portion of the probe beam reflected from the substrate and the second portion of the probe beam reflected from the substrate; the output beam includes the first portion of the probe beam transmitted through the substrate and the second portion of the probe beam transmitted through the substrate (i.e. column 3, line 39 to column 9, line 37).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. **Claims 15-17 and 45-52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein in view of Bernstein et al. ("Bernstein," US 5478750).

Klein does not specifically disclose a substrate having a second plurality of regions and concentric tracks, and a motor to spin the substrate.

In fig. 2, Bernstein discloses an apparatus for photometric analysis. The apparatus comprises a light source, a detector, and a substrate (20) that includes a first and second plurality of spaced-apart regions and concentric tracks and a motor (i.e. fig. 5, 80) to spin the substrate.

It would have been obvious to a person of ordinary skill in the art to modify Klein's substrate by including a second plurality of spaced apart regions and concentric tracks because it would be desirable to include regions on the substrate which can hold the samples to be analyzed. Furthermore, it would be obvious to a person of ordinary skill in the art to modify Klein's substrate by including a motor to spin the substrate since it would be desirable to have a mechanical means to spin the substrate to insure that the sample in the regions are thoroughly mixed.

Response to Arguments

9. Applicant's arguments filed 6/13/08 have been fully considered but they are not persuasive.

102 Rejection

In response to applicant's argument that Klein does not include "a first plurality of spaced-apart regions configured to bind the first analyte," as recited in claim 12, examiner respectfully disagrees. The Office takes the position that the recited claim language may be broadly interpreted. Based on this reasoning, the

Art Unit: 1797

hills on Klein's substrate (26, fig.1) may be broadly interpreted to be "a first plurality of spaced-apart regions."

In response to applicant's argument that Klein does not read on the language, "configured to bind the first analyte," "which illuminates the first plurality of spaced-apart regions," and, "is transmitted through the substrate to form the signal beam," as recited in claims 12 and 14, examiner respectfully disagrees. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. The above recited language is functional language, which is not sufficient subject matter to overcome the prior art.

In response to applicant's argument that Klein does not disclose a substrate that "includes a first surface lying substantially in a first plane and a second surface lying substantially in a second plane, the first plane being offset vertically from the second plane," as recited in claim 54, examiner respectfully disagrees. The Office takes the position that the recited claim language may be broadly interpreted. Based on this reasoning, Klein's hills, i.e. the top portion of the hill, include a first surface lying substantially in a first plane and a second surface, i.e. lower portion of hill, lying substantially in a second plane. Furthermore, the top and lower portions of Klein's hill are offset vertically from each other.

In response to applicant's argument that Klein does read on the language beginning with the term, "interacts," and "when," as recited in claim 55, examiner

Art Unit: 1797

respectfully disagrees. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. The language beginning with the term, "interacts," and "when," is functional language, which is not sufficient subject matter to overcome the prior art.

In response to applicant's argument that Klein does not disclose "the first and second portions of the probe beam being combined to produce the output beam," as recited in claim 55, examiner respectfully disagrees. The Office takes the position that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Based on the recited claim language, it appears that the structural limitations recited in claim 55 are the first and second portions of the probe beam, which appears to be disclosed by Klein. The combination of the first and second portions of the probe beam appear to recite the manner in which the claimed apparatus is intended to be employed, which is not sufficient subject matter to overcome the prior art.

Likewise, the language in claims 56 and 57 appear to recite functional language because the claims recite what the device does rather than recite what the device is. Since the invention is an apparatus-type of invention, the functional language recited in these claims are not sufficient to overcome the prior art.

Art Unit: 1797

103 Rejection

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Office takes the position that there is a motivation to combine the references, as stated in the prior Office action, filed on 12/31/07, and stated above, as follows: It would have been obvious to a person of ordinary skill in the art to modify Klein's substrate by including a second plurality of spaced apart regions and concentric tracks because it would be desirable to include regions on the substrate which can hold the samples to be analyzed. Furthermore, it would be obvious to a person of ordinary skill in the art to modify Klein's substrate by including a motor to spin the substrate since it would be desirable to have a mechanical means to spin the substrate to insure that the sample in the regions are thoroughly mixed.

In response to applicant's argument that neither Bernstein nor Klein, alone or in combination, read on the language recited in claim 15, examiner respectfully disagrees. As stated in the prior Office action, and stated above, Bernstein discloses a second plurality of regions in, i.e. fig. 2. Furthermore, the following

Art Unit: 1797

language, "configured to not bind the first analyte," is functional language, which is not sufficient subject matter to overcome the prior art.

In response to applicant's argument that neither Bernstein nor Klein, alone or in combination, read on the language recited in claim 16, examiner respectfully disagrees. As stated in the prior Office action, and stated above, Bernstein discloses a plurality of concentric tracks in, i.e. fig. 2. Furthermore, the following language, "such that the probe beam illuminates a single track," is functional language, which is not sufficient subject matter to overcome the prior art.

In response to applicant's argument that neither Bernstein nor Klein, alone or in combination disclose a controller configured to control on which track of the plurality of tracks the probe beam is incident, as recited in claim 17, examiner respectfully disagrees. As stated in the prior Office action, and stated above, Bernstein discloses a controller in, i.e. fig. 5, numeral 75. As to the "configured to," language recited after the term, "controller," the Office takes the position that such claim language is a recitation of the manner in which the claimed apparatus is intended to be employed, which does not differentiate the claimed apparatus from the prior art apparatus since the prior art apparatus teaches all the structural limitations of the claim.

In response to applicant's argument that neither Bernstein nor Klein, alone or in combination disclose an analyte bound to a substrate, as recited in claim 45, examiner respectfully disagrees. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. The

Art Unit: 1797

language beginning with the term, "illuminates," "interacts," and "indicates," is functional language, which is not sufficient subject matter to overcome the prior art.

In response to applicant's argument that neither Bernstein nor Klein, alone or in combination disclose "each of the first plurality of regions and the second plurality of regions are arranged in an alternating pattern," as recited in claim 46, examiner respectfully disagrees. Klein discloses a first plurality of regions and Bernstein discloses a second plurality of regions, as indicated in the prior Office action. Furthermore, as stated in the prior Office action, p. 5, it would have been obvious to combine both regions in any manner, i.e. alternating pattern, because it would be desirable to include regions on the substrate which can hold the samples to be analyzed.

In response to applicant's argument that neither Bernstein nor Klein, alone or in combination disclose "the first plurality of regions and the second plurality of regions form circular tracks," as recited in claim 47, examiner respectfully disagrees. As indicated in the prior Office action, Klein discloses a first plurality of regions and Bernstein discloses a second plurality of regions and circular tracks. Examiner has provided the proper motivation statement to combine both references, which is reiterated as follows: it would have been obvious to combine Klein and Bernstein because it would be desirable to include regions on the substrate which can hold the samples to be analyzed.

In response to applicant's argument that neither Bernstein nor Klein, alone or in combination disclose "the first plurality of regions and the second plurality of

Art Unit: 1797

regions form radially extending spokes on the substrate," as recited in claim 47, examiner respectfully disagrees. As indicated in the prior Office action, Klein discloses a first plurality of regions and Bernstein discloses a second plurality of regions, which appear to form radially extending spokes in fig. 2.

In response to applicant's argument that neither Bernstein nor Klein, alone or in combination disclose "the first plurality of regions and the second plurality of regions formed on the substrate by microfluidic printing," as recited in claim 48, examiner respectfully disagrees. The Office takes the position that the claim language in claim 48 appears to recite a product-by-process claim, which is of no patentable moment in an apparatus-type-of-claim.

In response to applicant's argument that neither Bernstein nor Klein, alone or in combination disclose that "the first plurality of regions and the second plurality of regions being arranged in a repeating pattern," as recited in claim 49, examiner respectfully disagrees. As indicated in the prior Office action, Klein discloses a first plurality of regions and Bernstein discloses a second plurality of regions. The combination of both regions would appear to form a repeating pattern.

In response to applicant's argument that neither Bernstein nor Klein, alone or in combination disclose a substrate where "the first plurality of regions has a first height and the second plurality of regions has a second height, the second height being offset relative to the first height," and "wherein the second height is offset relative to the first height by approximately one-eighth (or one-fourth) of a wavelength of the beam," as recited in claims 50-52, examiner respectfully

disagrees. Based on the disclosure of Klein's hills (i.e. first plurality of regions), it would appear that Klein's regions have a different height as compared to Bernstein's regions. Furthermore, it does not appear that applicant has provided a standard for determining these offset values based on a certain wavelength. Thus, it would appear that the height of Bernstein's regions is offset by either 1/4 or 1/8 of a wavelength of the beam relative to the height of Klein's regions.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone

Art Unit: 1797

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

Lore Ramillano
Examiner
Art Unit 1797